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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/734,583

12/15/2003

Hidetoshi Andou

2923-595

2600

6449

7590

10/23/2009

ROTHWELL, FIGG, ERNST & MANBECK, P.C.

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SUITE 800

WASHINGTON, DC 20005

EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1647

NOTIFICATION DATE

DELIVERY MODE

10/23/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/734,583	Applicant(s) ANDOU ET AL.	
	Examiner Marianne P. Allen	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's arguments filed 6/24/09 have been fully considered but they are not persuasive.

Claims 1-20 have been cancelled and claim 21 has been newly introduced.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection.

Claim 21 has been newly introduced. Basis is stated to be on pages 14-18 (sections (6)-(9)) of the specification. This is not agreed with.

There is no generic disclosure of producing a purified refolded monomeric MP52 with only the steps recited in claim 21. That is, pages 14-18 disclose the claimed steps; however, **there are additional steps that are not recited in the claims.** At least for example, the inclusion bodies were washed several times. (See page 15.) At least for example, the refolded monomeric MP52 was concentrated by ultrafiltration prior to isoelectric precipitation. (See page 16.) Note that original claim 7 includes this ultrafiltration as part of the purification process.

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Applicant may not pick and choose method steps from the example to arrive at a method not originally disclosed or contemplated.

It is appreciated that applicant is attempting to recite a method that has basis in parent application 10/048,458 so that the prior art of record cannot be applied against this claim. Application 10/048,458 was the national stage application of PCT/EP00/07600. This PCT published as WO 01/11041. Page 3 of the specification discloses the purification method of this document and **specifically distinguishes the method of the instant application from this prior purification method**. It is further noted that U.S. Patent 6,972,321 (which issued from 10/048,458) discloses additional steps not recited by the instant method. See at least for example, purification on a reversed phase column prior to refolding. See column 12, lines 26-30. Note that original claim 1 of the instant application discloses treating the solubilized monomer directly with a refolding solution. The instant application and parent application 10/048,458 disclose different purification protocols. Finally, the MP52 of the '321 patent purified in the example does not correspond to SEQ ID NO: 1 with an Ala at amino acid position 83. The MP52 of the '321 patent has an additional alanine at the N-terminus. See column 11, line 67, through column 12, line 18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 21 is rejected under 35 U.S.C. 103(a) as being obvious over Andou et al. (U.S. Patent No. 6,551,801) in view of Hotten et al. (U.S. Patent No. 6,972,321).

This rejection is maintained for reasons of record as applied to the prior claims. The presently claimed subject matter is not found in the parent applications for the reasons as set forth above. Both Andou et al. and Hotten et al. are by other as the inventive entities are not identical to that of the instant application and common ownership has not been established for reasons of record. They remain valid prior art against the instant claims.

It would have been obvious to purify the mutated MP52 protein of Hotten et al. using the purification method of Andou et al. One would have been motivated to do so to simplify purification of a desirable protein. Hotten et al. teaches the advantages of the mutated monomeric protein and Andou et al. teaches the advantages of the simplified purification steps.

Claim 21 is rejected under 35 U.S.C. 103(a) as being obvious over Andou et al. (WO 98/29559, published July 1998) in view of Hygene AG (EPO 1074620 A1, published February 2001).

This rejection is maintained for reasons of record as applied to the prior claims. The presently claimed subject matter is not found in any of the parent applications for the reasons as set forth above.

It would have been obvious to purify the mutated MP52 protein of HyGene AG using the purification method of Andou et al. One would have been motivated to do so to simplify

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purification of a desirable protein. HyGene AG teaches the advantages of the mutated monomeric protein and Andou et al. teaches the advantages of the simplified purification steps.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is (571)272-0712.

The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa